Initial assessment of the role of intra-aortic balloon pump during high-risk percutaneous coronary intervention

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ABSTRACT

Background: Intervention in high-risk patients with coronary artery disease has a low success rate and higher risk of complications. The intra-aortic balloon pump (IABP) is a recommended hemodynamic support device used in this patient population. However, there are still various opinions regarding the use of IABP.

Objective: (1) To describe clinical and subclinical characteristics of patients with high-risk percutaneous coronary intervention (PCI), (2) Evaluate the role of intra-aortic balloon pump (IABP) during high-risk PCI.

Materials and method: From August 2020 to October 2021, we conducted the study on 36 patient with high-risk coronary diseases in whom PCI, Among them, 16 patients underwent intervention under hemodynamic support of IABP.

Results: Thirty six patients (male 66,7%) join in the study (mean age 71,81±8,52 years). Common cardiovascular risk factors were hypertention (63,9%), smoking (47,2%) and diabetes (33,3%). The mean left ventricular ejection fraction was 34±9,71%. The mean SYNTAX score was 27,39±2,96. There were no significant differences in clinical and and subclinical characteristics between the group using and not using IABP during the intervention. In IABP group, the mean blood pressure after IABP support was significantly higher than baseline (88,31±7,39 mmHg vs 77,67±7,2 mmHg, p=0,001), the mean heart rate after IABP support was significantly lower than baseline (80,75±9,84 vs 83,93±12,66, p=0,007). The group supported by IABP had a higher rate of not using vasopressors, and the rate of using 1 vasopressor drug was less than the group without IABP support, statistically significant with p<0.05.

Conclusion: IABP can be use to support for high-risk PCI. Use of IABP reduces the proportion of patients requiring additional vasopressors to maintain hemodynamics.

I. INTRODUCTION

Percutaneous coronary intervention (PCI) is a widely used and highly effective method in treating patients with coronary artery disease. With the improvement of devices and interventionalist experience, the indications for PCI are expanding to include very complex lesions in specific populations. The consensus among interventionalists regarding the high-

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risk group of coronary artery disease patients includes a combination of patient characteristics such as advanced age, multiple comorbidities, with complex coronary artery lesions such as left main stem, calcified lesions, lesions in saphenous vein grafts, or triple-vessel disease, and in specific clinical settings such as acute coronary syndrome with cardiogenic shock or severe left ventricular dysfunction. For this high-risk patient population, the use of mechanical circulatory support devices during the intervention is recommended (1). The intra-aortic balloon pump (IABP) is a device that provides hemodynamic support through a counterpulsation mechanism. The balloon is inflated in the aortic root during systole and deflated during diastole. The IABP helps increase myocardial perfusion, decrease myocardial oxygen consumption, reduce afterload, and increase cardiac output. Several studies worldwide have shown that IABP is effective in reducing short-term and long-term cardiovascular events. However, there are not many studies on this issue in Vietnam. Therefore, we conducted a study with two objectives:

(1) To describe the clinical and paraclinical characteristics of high-risk patients with coronary artery disease.

(2) To preliminarily assess the role of IABP in supporting PCI in high-risk patients.

II. OBJECTIVES AND METHODS

Selection criteria:

- Patients identified as high-risk when undergoing percutaneous coronary intervention (PCI) include:

- Patients with a stenosis ≥ 70% in the left main coronary artery, with expected difficult and prolonged intervention, and with left ventricular ejection fraction (LVEF) dysfunction at any level. Or:

- Patients with severe left ventricular dysfunction (ejection fraction ≤ 35%), accompanied by a stenosis of the left main coronary artery or three major coronary arteries (≥ 50% stenosis in all 3 branches, with at least 1 branch having a stenosis ≥ 70%).

- Patients must agree to participate in the study.

Exclusion criteria:

- Patients with angiographic findings that do not meet the selection criteria.

- Patients with cardiogenic shock prior to angiography and PCI.

- Patients with mechanical complications: free wall rupture, ventricular septal rupture, acute severe mitral regurgitation due to chordal rupture.

- Patients with contraindications for intra-aortic balloon pump (IABP) placement: severe aortic regurgitation, aortic dissection, severe peripheral vascular disease.

- Patients with severe comorbidities.

- Patients who do not agree to participate in the study.

Study design: Prospective comparative intervention study. Convenience sample.

Study location: Vietnam National Heart Institute - Bach Mai Hospital.

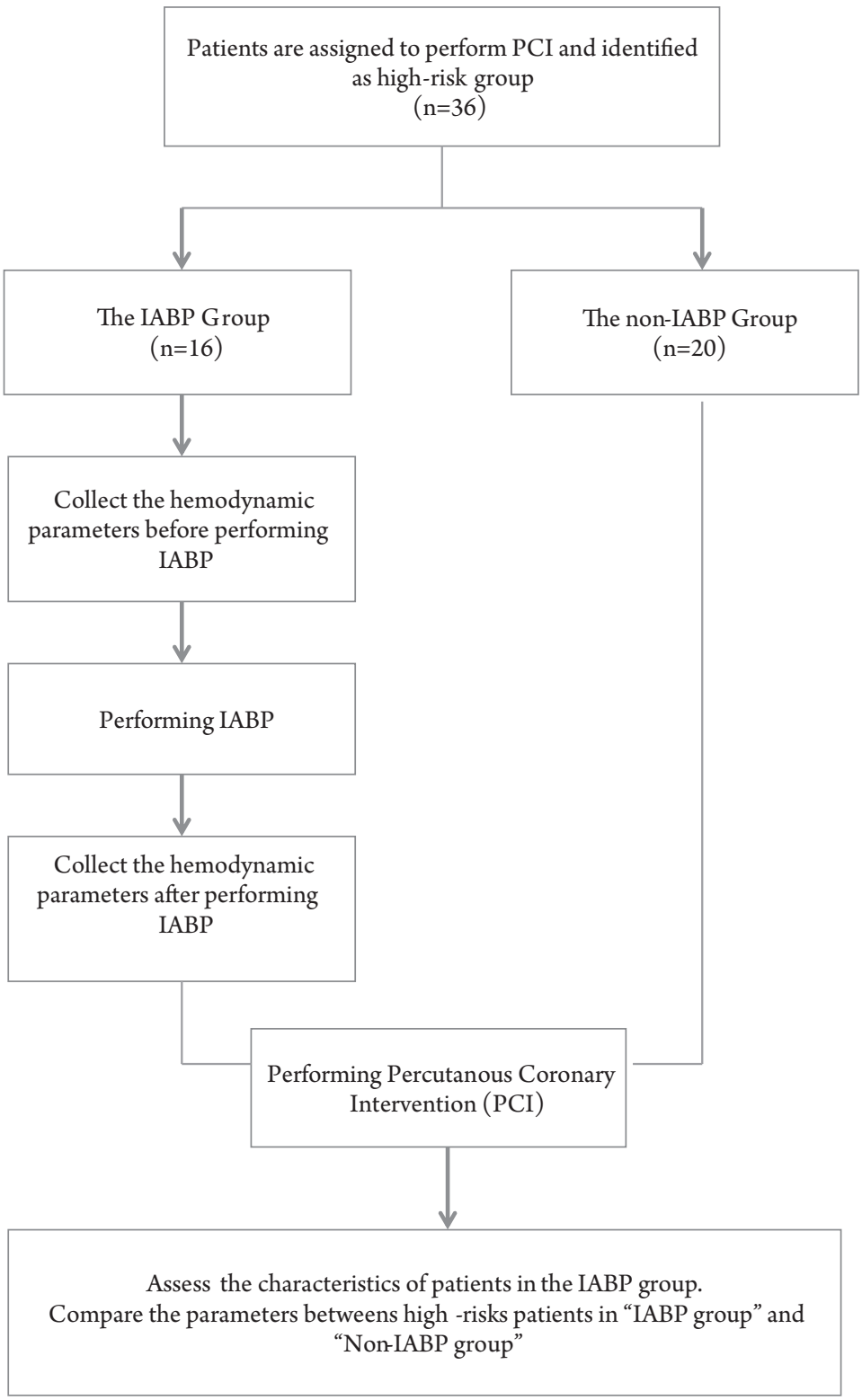
Research process:

Step 1: Collect clinical, laboratory and angiographic data of patients who meet the selection criteria.

Step 2: Perform PCI on patients. There are 2 groups of patients: 1 group uses IABP before the procedure, and 1 group does not use IABP. Record the parameters during the process.

Step 3: Evaluate the characteristics of the IABP group. Compare the parameters of the 2 groups.

Data analysis and processing: SPSS 20.0 software was used. T-test, chi-square and ANOVA tests were used if appropriate, $p < 0.05$ was considered statistically significant.


Patients are assigned to perform PCI and identified as high-risk group (n=36)
The IABP Group (n=16)
The non-IABP Group (n=20)
Collect the hemodynamic parameters before performing IABP
Performing IABP
Collect the hemodynamic parameters after performing IABP
Performing Percutanous Coronary Intervention (PCI)
Assess the characteristics of patients in the IABP group.
Compare the parameters betweens high -risks patients in "IABP group" and "Non-IABP group"

III. RESULTS

Table 1. The clinical characteristics of patients

	Sum n = 36	The IABP group n = 16	The non IABP group n = 20	p
The common characteristics				
Age X mean ± SD	71,81 ± 8,52	72,5 ± 8,14	71,25 ± 8,98	0,668
Male n (%)	24 (66,7)	11 (68,8)	13 (65)	0,813
BMI (kg/m^2) X mean ± SD	22,13 ± 2,36	22,88 ± 2,12	21,53 ± 2,42	0,09
BMI ≥ 23 (kg/m^2), n (%)	13 (36,1)	7 (43,8)	6 (30,0)	0,493
Risk factors				
Hypertension n (%)	23 (63,9)	10 (62,5)	13 (65)	0,877
Diabete n (%)	12 (33,3)	7 (43,8)	5 (25)	0,236
Smoking, n (%)	17 (47,2)	8 (50,0)	9 (45,0)	0,765
Stroke n (%)	6 (16,7)	2 (12,5)	4 (20,0)	0,672
Performance PCI n (%)	6 (16,7)	2 (12,5)	4 (20,0)	0,672
Chornic kidney disease (CKD) n (%)	7 (19,4)	2 (12,5)	5 (25)	0,426
Heart Failure n (%)	12 (33,3)	6 (37,5)	6 (30)	0,635

Between August 2020 and October 2021, 36 patients were included in the study. The average age of the patients was 71.81±8.52 years, with the majority being male (66.7%). The average BMI of the patients was 22.13±2.36, with 13 patients (36.1%) having a BMI ≥23. The most common cardiovascular risk factors were hypertension (63.9%), smoking (47.2%), and diabetes (33.3%). There was no statistically significant difference between the group that used IABP and the group that did not use IABP.

Table 2. The subclinical characteristics of patients and Syntax Score

	Sum n = 36	The IABP group n = 16	The non IABP group n = 20	p
Biochemical parameters				
Ure (mmol/L) X mean ± SD	6,73 ± 2,37	6,82 ± 2,52	6,66 ± 2,31	0,835

Glucose (mmol/L) X mean ± SD	8,33 ± 4,08	8,31 ± 4,39	8,15 ± 3,95	0,914
Creatinin (µmol/L) X mean ± SD	87,00 ± 31,11	87,19 ± 27,23	86,85 ± 34,61	0,975
GOT (U/L) X mean ± SD	101,36 ± 98,44	106 ± 97,46	97,60 ± 81,59	0,802
GPT (U/L) X mean ± SD	58,00 ± 42,12	57,94 ± 40,68	58,05 ± 41,74	0,996
Cholesterol (mmol/L) X mean ± SD	4,50 ± 0,96	4,43 ± 0,84	4,56 ± 1,07	0,680
LDL – C (mmol/L) X mean ± SD	2,49 ± 0,99	2,59 ± 1,13	2,41 ± 0,89	0,603
HDL – C (mmol/L) X mean ± SD	1,23 ± 0,45	1,34 ± 0,60	1,14 ± 0,26	0,195
Triglycerid (mmol/L) X mean ± SD	1,91 ± 1,63	2,15 ± 2,31	1,72 ± 0,76	0,425
Natri (mmol/L) X mean ± SD	137,83 ± 3,07	138,00 ± 3,48	137,70 ± 2,79	0,776
Kali (mmol/L) X mean ± SD	3,90 ± 0,49	4,00 ± 0.39	3,82 ± 0,55	0,293
Clo (mmol/L) X mean ± SD	100,64 ± 3,73	100,87 ± 4,05	100,45 ± 3,54	0,739
Troponin T (ng/L) Median {IQR}	252,60 {37,8–1455}	137,50 {36,0–2142,3}	322 {60,8– 957,3}	0,502
NT – ProBNP(pmol/L) X mean ± SD	555,26±513,45	487,91 ± 450,1	609,14 ± 564,64	0,489
CBC parameters				
Hồng cầu (T/L) X mean ± ĐLC	4,41 ± 0,65	4,19 ± 0,54	4,58 ± 0,69	0,071
Hemoglobin (g/L), X mean ± ĐLC	125,03 ± 15,43	125,00 ± 13,94	125,95 ± 16,88	0,992
Bạch cầu (G/L) X mean ± ĐLC	9,42 ± 3,15	8,44 ± 2,18	10,19 ± 3,61	0,097
Tiểu cầu (G/L) X mean ± ĐLC	282,19±112,71	303,56±141,92	265,10 ±82,52	0,316
Echocardiology				
LVEF (%) X mean ± ĐLC	34,00 ± 9,71	33,12 ± 6,48	34,70 ± 11,82	0,636
LVEF ≤35% n (%)	28 (77,8)	12 (75)	16 (80)	0,720

Syntax Score				
<33 n (%)	32 (88,9)	14 (87,5)	18 (90)	0,608
≥ 33 n (%)	4 (11,1)	2 (12,5)	2(11,1)	
SYNTAX score X mean ± SD	27,39 ± 2,96	27,44 ± 3,18	27,35 ± 2,85	0,931

The average left ventricular ejection fraction (LVEF) of the patients in the study is 34±9.71%. Common myocardial injuries were found in 9 patients (56.25%), while triple-vessel disease was found in 7 patients (43.75%). The average SYNTAX score was 27.39±2.96. Among them, 32 patients had SYNTAX scores ranging from 22-32 (88.9%). There was no statistically significant difference between the group that used an intra-aortic balloon pump (IABP) and the group that did not use an IABP.

Chart 1. Sub-groups of patients following the lesions on the DSA of cononary artery in combination with the ejection fraction of left ventricular.

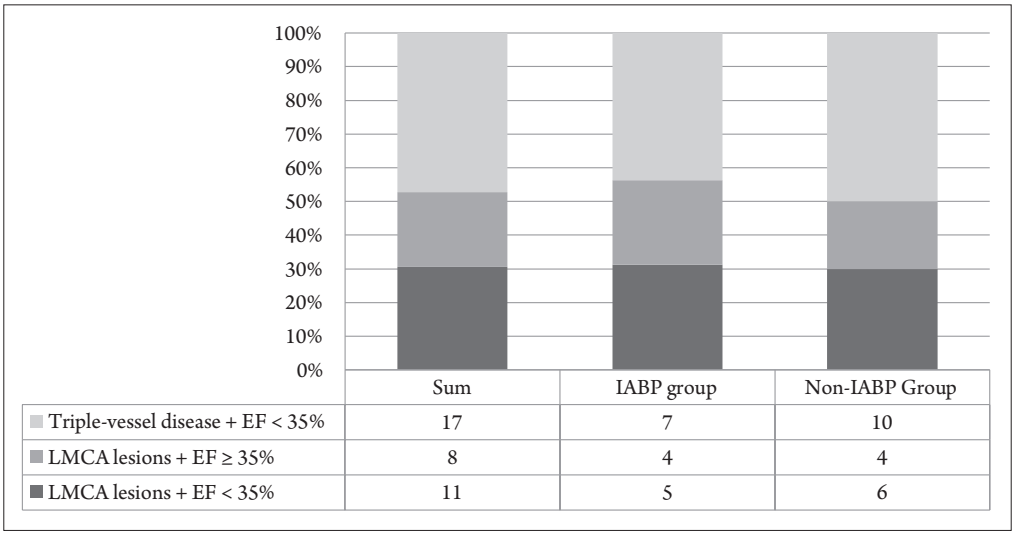


Table 3. Some changes of parameters after performing IABP or PCI.

The parameters	**Before IABP**	**After IABP**	**P**
Mean Arterial Pressure, mmHg (TB±SD)	77,67±7,20	88,31±7,39	0,001
Heart rate, bmp (TB±SD)	83,93±12,66	80,75±9,84	0,007
The parameter	**Before PCI**	**After PCI**	**P**
Creatinin, µmol/L (TB±SD)	87,19±27,23	88,81±24,37	0,547

After the placement of an intra-aortic balloon pump (IABP), the average blood pressure increased from 77.67±7.2 mmHg to 88.31±7.39 mmHg, p=0.001. The heart rate decreased from 83.93±12.66 beats per minute to 80.75±9.84 beats per minute, p=0.007. There was no statistically significant difference in the creatinine level before and after the intervention, p=0.547.

Table 4. The comparison of parameters between "the group IABP" versus "the non-IABP group" during intervention

	Sum n = 36	The IABP group n = 16	The non-IABP group n = 20	p
Site of lesions				
Left main coronary artery (LMCA), n (%)	18 (50)	9 (56,25)	9 (45)	0,502
LAD, n (%)	9 (25)	4 (25)	5 (25)	1,000
LCx, n (%)	2 (5,6)	1 (6,25)	1 (5,0)	0,871
RCA, n (%)	7 (19,4)	2 (12,5)	5 (25)	0,426
Number of stents used				
The mean of stents	1,89	2,00	1,80	0,408
1 stent, n (%)	11 (30,6)	3 (18,75)	8 (40)	0,156
2 stents, n (%)	18 (50,0)	10 (62,5)	8 (40,0)	0,180
3 stents, n (%)	7 (19,4)	2 (12,5)	5 (25,0)	0,631
Number of inotropic drugs used				
None	20 (55,6)	13 (81,25)	7 (35,0)	0,008
1 Inotropic drug	14 (38,9)	2 (12,5)	12 (60,0)	0,006
2 Inotropic drugs	2 (5,6)	1 (6,25)	1 (5)	0,871
Time of hospitalization				
Days X mean ± SD	5,69 ± 2,38	6,31 ± 2,94	5,2 ± 1,73	0,166
Main outcomes				
Death, n (%)	3 (8,3)	1 (6,25)	2 (10,0)	0,585
Hospital discharge, n (%)	33 (91,7)	15 (93,75)	18 (90)	

The group that used an intra-aortic balloon pump (IABP) had a statistically significant lower rate of requiring multiple vasopressors and a higher rate of using a single vasopressor than the group that did not use an IABP, with $p<0.05$.

IV. DISCUSSION

We conducted a study on 36 patients identified as high-risk coronary artery disease undergoing percutaneous intervention. High-risk coronary artery disease was defined as patients with severe stenosis in the left main coronary artery with a risk of hemodynamic collapse or those with a left ventricular ejection fraction ≤35% with significant stenosis in all three coronary arteries. The mean age of the patients in the study was 71.81±8.52 years, and males accounted for 66.7% of the patients. Our results are consistent with other studies that found that patients with high-risk coronary artery disease have a mean age of >60 years and are predominantly male. Perera et al. found a mean age of 71±9.5 years with 79.4% males in their study of 301 high-risk coronary artery disease patients (2). Briguori et al. reported a mean age of 65.6±9.7 years with 88.6% males in their study of high-risk coronary artery disease patients (3). The common cardiovascular risk factors in our study were hypertension (63.9%), smoking (47.2%), and diabetes (33.3%). These were

also the high-risk factors in other studies. Perera et al. reported hypertension and diabetes rates of 61.8% and 35.2%, respectively, in their study (2). Mishra et al. found that hypertension accounted for 72.2% and diabetes accounted for 43.8% of their patients (4). In addition, 36.1% of our patients had a BMI ≥23 (kg/m2), indicating that more than one-third of the patients were overweight according to the classification for Asian people (5).

The average LVEF on echocardiography is 34.00 ± 9.71%, with severe reduction according to the American Society of Echocardiography 2015 guidelines (6). Reduced LVEF is an independent prognostic factor for mortality in patients undergoing coronary intervention. Mamas' study on the impact of left ventricular function on the outcomes of PCI showed that patients with LVEF <30% had a 7.25-fold higher mortality rate, while those with LVEF 30-40% had a 2.9-fold higher mortality rate compared to patients with LVEF >50%, with a statistically significant difference with p <0.0001 (7). All patients in our study had complex coronary artery disease, with involvement of all three coronary arteries or severe stenosis at the left main stem. The more complex the coronary artery disease, the higher the incidence of cardiovascular events during intervention. The average SYNTAX score of patients was 27.39 ± 2.96. The SYNTAX score is used to assess the complexity of coronary artery disease, with higher scores indicating greater complexity and more cardiovascular events during intervention (8). Combined with the high average age, high cardiovascular risk factors, and low ejection fraction, the study population had a high risk of hemodynamic collapse during coronary intervention, and the use of hemodynamic support devices in these patients was necessary and appropriate.

Currently, IABP is inserted into the aorta through the skin, usually from the femoral artery using the Seldinger technique. In our study, 100% of IABP placement procedures were successfully performed. After the intervention process is completed, if the patient's arterial blood pressure is stable and no additional vasopressors are required, the balloon is immediately removed in the intervention room. If the arterial blood pressure still needs support, the balloon will be maintained and moved with the patient to the intensive care unit for monitoring, and removed when the arterial blood pressure improves. The use of IABP significantly increased the mean arterial blood pressure of patients in the study from 77.67±7.20 mmHg to 88.31±7.39 mmHg (p=0.001) and significantly reduced the mean heart rate from 83.93±12.66 beats per minute to 80.75±9.84 beats per minute (p=0.007). According to Akyurekli's study on the determination of factors affecting cardiac oxygen consumption and the effectiveness of IABP in reducing cardiac load during systole, it was found that IABP reduced heart rate and increased left ventricular ejection fraction (9). Tran Duy Anh's study also reported the effectiveness of IABP in reducing heart rate and increasing mean arterial blood pressure in subjects with heart failure supported by IABP (10).

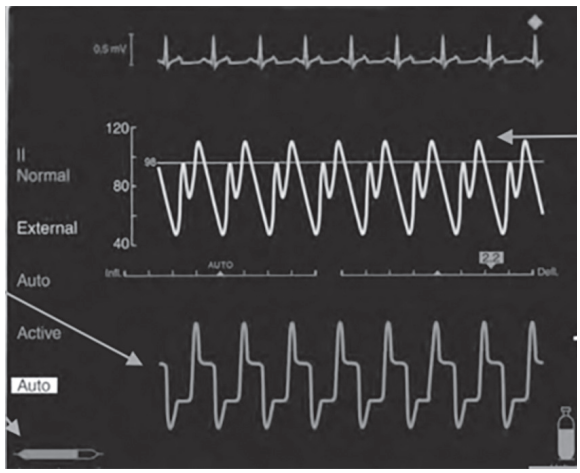


Figure 2. IABP 1:1

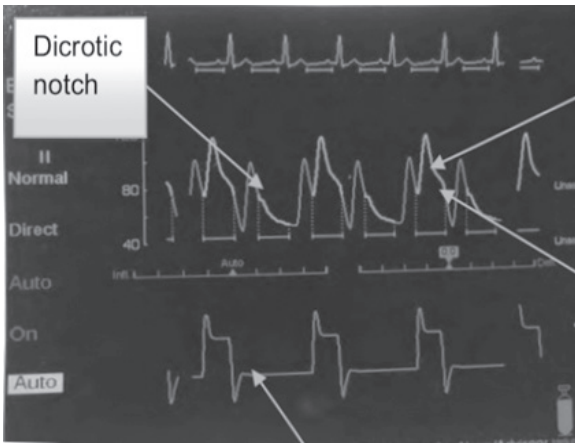


Figure 3. IABP 1:2

The support of IABP through the pump operation of the balloon during the period of diastolic helps increase coronary artery perfusion, increase blood flow through narrow vascular injuries to nourish the heart muscle. During the cardiac relaxation period, the balloon is quickly deflated to create negative pressure in the main artery to reduce afterload, increase the flow index, and reduce the cardiac workload, thereby reducing the demand for myocardial oxygen consumption. The presence and operation of IABP may reduce the risk of hypotension and the need for additional vasodilator drugs to maintain blood pressure. In our study, 81.25% of patients in the IABP-supported group did not need additional vasodilator drugs during and after the intervention, compared to 35% in the non-IABP group, with a significant difference at p=0.008. Perera et al., when comparing two high-risk PCI intervention groups with or without active IABP use, noted that in the non-IABP group, 18 patients (12%) had to undergo emergency IABP placement during the intervention, with 13 patients due to hypotension and one patient due to pulmonary edema. These patients did not differ from patients who did not require emergency IABP placement in terms of clinical characteristics and left ventricular ejection fraction, but had a significantly higher incidence of coronary artery injury (2). Briguori's study reported a 15% incidence of hypotension in high-risk coronary artery intervention patients who did not receive IABP support (3). Mishra reported a 22% mortality rate in the hospital in the group of high-risk coronary artery intervention patients who received IABP rescue due to complications of the intervention process (4). With a relatively high proportion of patients in the non-IABP group experiencing hemodynamic disorders and requiring emergency IABP placement (15% in Briguori's study, 12% in Perera's study), it underscores the importance of preventative strategies for mechanical circulatory support devices, including IABP, during high-risk PCI interventions. Therefore, IABP still plays a necessary role as a support device recommended by the World Heart Association for high-risk coronary artery interventions.

V. LIMITATIONS OF THE STUDY

Our study has some limitations. Firstly, the sample size of the study is modest due to strict selection criteria and a short study duration. Secondly, the patient grouping was not randomized, and the decision to use IABP depended on the operator's choice, which is also a limitation of the study.

VI. CONCLUSION

IABP should be used to support interventions in high-risk coronary artery disease patients to improve hemodynamics during the procedure. The use of IABP reduces the proportion of patients who require additional vasopressor medications to maintain hemodynamics

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